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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,695	05/21/2002	Yukoh Hiei	0760-0305P	5501

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EXAMINER
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WORLEY, CATHY KINGDON

ART UNIT	PAPER NUMBER
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1638

NOTIFICATION DATE	DELIVERY MODE
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12/16/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/089,695	<b>Applicant(s)</b> HIEI ET AL.	
	<b>Examiner</b> CATHY K. WORLEY	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,12,14,15,17,19-21,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,12,14,15,17,19-21,23 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Request for Continued Examination***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 24, 2008, has been entered.

### ***Status of the Claims***

2. Claims 2-11, 13, 16, 19, 22, and 25 have been cancelled.
3. Claims 1, 12, 14, 15, 17, 18, 20, 21, 23, and 24 are pending and are examined in this Office Action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 12, 14, 15, 17, 18, 20, 21, 23, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are included in this rejection.

The term "promoting efficiency" in claim 1 is a relative term which renders the claim indefinite. The term "promoting efficiency" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Does this mean an increase in transformation of heated treated cells or tissues compared to non-heat treated cells or tissues? Does this mean an increase in transformation of cells or tissues subjected to centrifugation relative to cells or tissues that were not centrifuged? Does this mean increasing transformation efficiency relative to other types of plants or plant tissues? Does this mean an increase in efficiency relative to plants that were treated with bacterium that do not belong to the genus *Agrobacterium*?. The term "promoting efficiency" implies there is an increase in gene transfer efficiency, and it is unclear what the increase is relative to.

5. Claims 1, 12, 14, 15, 17, 18, 20, 21, 23, and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for promoting efficiency of gene transfer into rice plant embryos that includes a step of incubating immature embryos of rice for 5 minutes at 46°C and being enabling for a method for promoting efficiency of gene transfer into maize embryos that includes a method step of incubating the embryos for 3 minutes at 46°C and being enabling for a method for promoting efficiency of gene transfer into bent grass calli that includes a method step of incubating the calli for 5 minutes at 46°C does not reasonably provide enablement for a method for promoting efficiency of gene transfer into plant embryos, plant calli or cultured plant cells that utilizes different incubation times and temperatures or for a method that utilizes a different type of plant tissue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the

relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to a method for promoting efficiency of gene transfer into plant embryos, plant calli or cultured plant cells that utilizes a step of heating plant cells or tissues to 37°C - 52°C for 1 minute to 24 hours.

Applicants teach increased transformation efficiency of rice embryos that were incubated for 5 minutes at 46°C and of maize embryos that were incubated for 3 minutes at 46°C and of bent grass calli that were incubated for 5 minutes at 46°C relative to the same types of plant tissues that were not heated to 46°C (see working examples).

Applicants do not teach the incubation of any other type of plant tissue or cell or the incubation at any temperature other than 46°C or incubation times other than 3 minutes or 5 minutes.

For example, the state-of-the-art is such that one of skill in the art cannot predict which combination of tissue-type, incubation temperature, and incubation time will result in an increase in efficiency of gene transfer. For example, in the prior art (Plant Phys. (1983) Vol. 72; pp. 817-820) Wu et al teach that incubation of pear suspension cells at temperatures above 42°C for 20 minutes resulted in injury to the suspension cells (see page 818, Figure 3A). This would indicate a harmful effect rather than a beneficial effect from the heat treatment; and therefore it would not promoter efficiency of gene transfer. Wu et al also teach that incubation of pear

suspension cells at 40°C resulted in injury to the cells when the incubation times were increased, with over 70% of the cells becoming injured after 3 hours (see Figure 3 B).

Furthermore, the Applicant's own data that was submitted in the form of a declaration on Oct. 24, 2008, demonstrates that different combinations of temperatures and incubation times yielded different results for immature rice embryos (see page 8 of the declaration). Many of the combinations did not result in an increase in efficiency at all (see data points with relative GUS expression of 1), and some of the data points were actually detrimental (see 10 minutes at 49°C and 60 minutes at 46°C).

Clearly a method that utilizes a step of heating plant cells or tissues to 37°C - 52°C for 1 minute to 24 hours can not reliably result in promoting efficiency of gene transfer.

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of skill in the art to perform trial and error experimentation using different plant tissues and different temperatures and incubation times; many of which would result in no gene transfer at all; in an attempt to optimize the procedure to generate a protocol that results in increased efficiency of gene transfer.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed

above, undue experimentation would be required to practice the claimed invention, and therefore, the invention is not enabled throughout the broad scope of the claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 12, 14, 15, 17, 18, 20, 21, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (WO 98/54961, published December 10, 1998), in view of Lyznik et al (The Plant Journal (1995) Vol. 8; pp. 177-186). The Applicants arguments and evidence have been fully considered but were not found to be persuasive.

The claims are directed to a method of “promoting efficiency” of gene transfer via *Agrobacterium* to plant cells /tissues, comprising the steps of heating and centrifuging the plant cells, wherein the contact between the plant cells and *Agrobacterium* occurs after or while heating and/or centrifugation.

Hansen teaches a method of gene transfer to maize by *Agrobacterium* comprising heating the maize calli at 45°C for 4 minutes (see page 19, first paragraph). After the heat treatment, the medium was replaced by an



Agrobacterium suspension, therefore, the maize calli are contacted with Agrobacterium (see first and second paragraph on page 19). Maize plants are monocotyledons and angiosperms and belong to the family Gramineae.

Hansen does not specifically teach centrifugation from 1000G to 150,000G for 1 second to 4 hours. Hansen is silent about what particular technique was utilized to replace the medium with the Agrobacteria suspension.

Lyznik et al teach that maize protoplasts are harvested in Eppendorf tubes by centrifugation for 5-10 seconds at 1000 g (see last paragraph on page 183) and the medium was replaced with extraction buffer.

At the time the invention was made, it would have been obvious and within the scope of one of ordinary skill in the art to modify the method taught by Hansen to centrifuge the cells to facilitate changing the buffer/medium. This is an obvious variation of the method taught by Hansen, because centrifugation to settle cells into a pellet to facilitate removal of the liquid medium was well known in the art at the time of filing, as evidenced by the teaching of Lyznik et al.

The Applicant argues that the combination of heating and centrifugation provided unexpected results by yielding increased GUS expression compared to controls (see page 3 of the response filed on Oct. 24, 2008).

The Examiner agrees that the working examples have demonstrated unexpected results, however, the claims are not commensurate in scope with the scope of the unexpected results, because the wide range of types of plant tissue

being claimed, the very wide range of temperatures and incubation times, and the very wide range of centrifugational speeds and times.

The Applicant has provided data in the form of a declaration submitted on Oct. 24, and the data do not support the breadth of the claims. The data have shown only two centrifugal speeds, and the speed of 20,000G was only performed for 1 second (see Figure 2 on page 5 of the declaration); however the claims continue to recite centrifugation up to 150,000G for 4 hours. Furthermore, the data for heating show that different combinations of temperatures and incubation times yielded different results for immature rice embryos (see page 8 of the declaration). Many of the combinations did not result in an increase in efficiency at all (see data points with relative GUS expression of 1), and some of the data points were actually detrimental (see 10 minutes at 49°C and 60 minutes at 46°C). However, the claims continue to encompass heating plant cells or tissues to 37°C - 52°C for 1 minute to 24 hours.

Therefore, the limited showing of unexpected results is not sufficient to support the breadth of the current claims.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHY K. WORLEY whose telephone number

is (571)272-8784. The examiner can normally be reached on M-F 10:00 - 4:00, with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Cathy K. Worley/  
Primary Examiner, Art Unit 1638